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14. ABSTRACT

Musculoskeletal system conditions are the leading cause of hospitalization and disability for the U.S. Armed Forces. The Department of Defense pays over $1.5 billion per year to disabled service members, and musculoskeletal conditions account for 40-50% of this amount. This study investigates the effectiveness of an interdisciplinary functional restoration approach to the treatment of Active Duty military from all 4 branches suffering from chronic musculoskeletal pain (CMP). The primary aims of this Functional and Occupational Rehabilitation Treatment (FORT) Program include restoring physical function, retaining soldiers on active duty, and increasing the participants' abilities to effectively manage their pain. These outcomes, as well as socioeconomic variables, are evaluated immediately following treatment, and at 6, 12, and 18 months follow-up.

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musculoskeletal; disability; pain; functional restoration; treatment outcomes; cost-effectiveness; interdisciplinary

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INTRODUCTION:

Musculoskeletal system conditions are the leading cause of hospitalization and disability for the U.S. Armed Forces. The Department of Defense pays over $1.5 billion per year to disabled service members, and musculoskeletal conditions account for 40-50% of this amount. The medical discharge of one active duty U.S. military member in their twenties has been estimated to cost the government approximately $250,000 in lifetime disability costs, excluding health-care costs. Despite continuous advances in military medicine, the rates of disability cases within the U.S. military have been increasing at an alarming rate, and nearly doubled between 1985 and 1994. Fortunately, numerous studies with civilian populations have demonstrated the efficacy of an interdisciplinary chronic pain rehabilitation program (ICPRP) at facilitating return-to-work in workers' compensation patients with occupational musculoskeletal disorders and work disability. Return-to-work rates with this population administered ICPRP often approach 80-85% at one year, compared to no-treatment or standard care comparison groups that demonstrate only a roughly 40% return-to-work.

Without changes in the current approach to the treatment of musculoskeletal conditions, recognized trends of increasing disability rates and tremendous associated costs will very likely continue in the future. Thus, there is a clear need for clinical research to develop evidence-based assessment and treatment approaches to decrease the enormous costs associated with chronic musculoskeletal conditions within the U.S. Armed Forces. The purpose of this study is to evaluate the effectiveness of an ICPRP designed to decrease chronic musculoskeletal pain, increase functioning, and retain military members on active duty. The major hypothesis is that the ICPRP will significantly increase the likelihood that active duty military personnel suffering from musculoskeletal disorders will remain on active duty and be fully qualified to perform all of their military duties, as well as positively impact other socioeconomic outcomes. All participants are active duty military members recruited from all four branches of the military and treated at Wilford Hall Medical Center at Lackland Air Force Base, Texas.

This is a pre-to post-treatment evaluation design, with evaluations conducted immediately before and after treatment, as well as at 6-, 12-, and 18-month follow-up periods in order to determine differential outcomes on variables such as return to full duty status, work retention, and additional health-care utilization. The specific aims of the study are to evaluate the efficacy of ICPRP in reducing patient-reported pain symptoms, unnecessary health-care utilization, health-care costs, and number of military members on medical profile, disability, or separated from active duty. Additional aims include improving functioning, increasing the number of military members remaining fit for duty and worldwide qualified, and increasing military members' ability to pass their physical fitness test for their respective military service. In summary, this research project addresses the clear need for clinical research to develop evidence-based assessment and treatment approaches to decrease the enormous cost associated with chronic musculoskeletal conditions within the U.S. Armed Forces.

BODY:

The following is an outline of progress pertinent to the tasks outlined in our statement of work:

Hire and train treatment team members – All grant-related personnel were hired as of December 2003 and trained by the Principal and Co-Investigators. Ongoing supervision of study personnel

is accomplished through weekly meetings with Dr. Peterson (PI), regular telephone contact with Dr. Gatchel (PI), and frequent site visits by Dr. Gatchel. Day-to-day project management is accomplished through the study coordinator, Dr. McGeary, who reports to the PIs. Protocol questions or concerns are brought up with the PIs for discussion as soon as possible.

Oversee the implementation of the interdisciplinary treatment program and guide any necessary changes to the treatment protocol – The interdisciplinary treatment program (dubbed the Functional Occupational Rehabilitation Treatment –FORT-- program) has been implemented at Wilford Hall Medical Center and has been running since January 2004. The program is overseen by Dr. McGeary and problems/required changes are addressed to the PIs. If Drs. Gatchel and Peterson deem a change necessary, it is addressed to the IRBs of record for consideration through amendments to the original protocol. To date, six amendments have been submitted, with only one submitted in 2005. The amendments submitted in the past year include:

> *17 FEB 2005*: Request for printing an article about the program in the Air Force and Army Times

Coordinate and oversee the development and maintenance of the study database,e including quality assurance and database security in compliance with HIPAA and DoD regulations – The database for the FORT program was established in December 2003 with assistance from technical support personal at the University of Texas Southwestern Medical Center at Dallas and Wilford Hall Medical Center. Presently, the database exists as a password-protected and encrypted Microsoft Access database. Access is only available to Dr. McGeary and his on-site study staff at Wilford Hall Medical Center (Christin Pasker, Karen LeRoy, Mysti Clifton). It is housed on a single computer located in a locked office on the fourth floor of Wilford Hall. Data coding sheets have been developed to minimize errors in data interpretation and all study staff have been trained in data coding. Data quality is monitored bi-weekly by the study coordinator through a review of data coding sheets and the database. This is further supported through monthly interrater reliability checks in which Dr. McGeary re-codes 10% of the records input for that month and compares his entries with those of the previous coder.

Enroll 90 patients as established by the study protocol – As of 20 January 2006, we have enrolled 53 participants in the study protocol. Twenty-three of those participants were enrolled in the past year. Study enrollment is ongoing and we expect to reach our final goal of 90 participants (nine more have already been enrolled between 20 January 2006 and the first week of February 2006). Randomization checks confirm that we have managed to balance our enrolled participants between the Treatment-As-Usual (TAU) and FORT groups to ensure that they are comparable. This has been accomplished through the use of block randomization controlling for site of injury, length of disability, and gender. A summary of existing participant demographics is included below:

Variable	Level	
Group	*FORT*	20
	TAU	21
	Pending Randomization	11
Branch of Service	*Army*	17
	Air Force	34

	Navy	1
Gender	*Male*	33
	Female	19
Race	*Asian*	2
	African American	9
	Caucasian, not Hispanic	37
	Hispanic	3
	Other	1
Rank	*Enlisted (E1-E9)*	44
	Officer (O1-O10)	8
Site of Pain	*Lumbar*	38
	Thoracic	2
	Cervical	4
	Multiple Spinal	3
	Upper Extremity	2
	Lower Extremity	3

At the time of this report, one participant had been consented but had not yet completed assessment materials, so the total number of participants reviewed above is 52.

Demographics have been periodically analyzed after randomization to ensure equal distribution of participants across the two study groups. The following is the most recent analysis of the 41 participants who have been randomized and treated in this study:

Demographic	**Levels**	**FORT** (% in grp)	**TAU** (% in grp)	**Significance Level ***
Branch of Service	*Army*	3 (15%)	9 (43%)	NS
	Air Force	17 (85%)	11 (52%)	
	Navy	0 (0%)	1 (5%)	
Gender	*Male*	13 (65%)	12 (57%)	NS
	Female	7 (35%)	9 (43%)	
Race	*Asian*	1 (5%)	1 (5%)	NS
	African American	2 (10%)	5 (23%)	
	Caucasian, Non-Hispanic	14 (70%)	14 (67%)	
	Hispanic	2 (10%)	1 (5%)	
	Other	1 (5%)	0 (0%)	
Rank	*Enlisted*	18 (90%)	17 (81%)	NS
	Officer	2 (10%)	4 (19%)	
Site of Pain	*Lumbar*	14 (70%)	15 (71%)	NS
	Thoracic	1 (5%)	1 (5%)	
	Cervical	2 (10%)	1 (5%)	
	Multiple Spinal	1 (5%)	2 (10%)	
	Upper Extremity	2 (10%)	0 (0%)	
	Lower Extremity	0 (0%)	2 (0%)	

** NS = no significant differences among variables based on Chi-square analyses*

Problems and Set-backs: We had originally hoped to complete all of our initial recruitment, treatment, and assessment by the end of the third year as stated in our proposal. It should be noted that, because of the Iraqi war during the first part of 2003 and continuing to the present, there was a major deployment of personnel from Wilford Hall Medical Center. This interfered somewhat with the early implementation of all aspects of initial activities of YEAR 01, and continuing deployments also impacted some aspects of YEARS 02 and 03. Some potential participants found it difficult to leave their duty stations long enough to participate in a study of this magnitude, making it somewhat difficult to meet our recruitment goals as quickly as we hoped. However, we have recruited tirelessly through a variety of mechanisms with success, and we are totally confident that our final recruitment goal of 90 participants will ultimately be met.

KEY RESEARCH ACCOMPLISHMENTS:

- Development of a comprehensive musculoskeletal pain database tapping over 100 variables
- Development and implementation of participant recruitment protocol
- Development and implementation of interdisciplinary chronic musculoskeletal pain treatment program at Wilford Hall Medical Center
- Development and implementation of treatment quality assurance protocol
- Development and implementation of data quality assurance protocol
- Development and training of comprehensive research team employing a Physical Therapist, Registered Nurse, and Clinical Psychologist
- Recruitment of 53 participants as of 21 January 2006
- At the time of this report, 4 participants have completed 1-year follow-up measures and 10 have completed 6-month follow-up measures
- Data gathering is ongoing, so there have been no publications of note to date. However, the FORT program has been covered in news stories through the Wilford Hall Medical Center newsletter (Vital Signs), The Air Force and Army Times, and the Armed Forces Television Network

REPORTABLE OUTCOMES:

In line with our Statement of Work, we have periodically examined our study data to determine the efficacy of the FORT treatment compared to the Treatment-As-Usual group. A summary of our outcomes is presented in the table below. Because our database allows us to examine over 200 variables, we have included just a handful of relevant outcomes for the purposes of this progress report. When examining the table below, please keep in mind the assessment intervals utilized for this project:

- **Pre-Anesthesiology**: assessment completed immediately after randomization and before all participants are followed through 4 weeks of just Anesthesiology pain care treatment (this is a *pre-treatment* interval)
- **Pre-FORT**: assessment completed after the 4-week Anesthesiology follow-up, right before the FORT participants begin participation in the FORT program (this is also a *pre-treatment* interval)
- **Post-FORT**: assessment completed after the 3-week FORT interval (this is a *post-treatment* interval)

Also, in preparation for data review, a list of the included measures is listed below with explanations of the domains assessed:

- **Pain VAS**: visual analog pain scale rating, ranging from 0 (no pain) to 10 (extreme pain)
- **MVAS**: a measure of self-reported physical disability. Score ranges include 0 (no disability), 1-40 (Mild disability), 41-70 (Moderate disability), 71-100 (Severe disability), 101-130 (Very Severe disability), 131-150 (Extreme disability)
- **BDI-2**: a measure of depressive symptomatology. Score ranges include 0-13 (Minimal depression), 14-19 (Mild depression), 20-28 (Moderate depression), 30+ (Severe depression)
- **Lift-FW**: floor-to-waist lifting capacity in pounds
- **Lift-WE**: waist-to-eye-level lifting capacity in pounds
- **SF-36 PCS**: a measure of health-related quality of life. The Physical Composite Score measures the impact of one's physical health on his or her life. The measure mean is 50, with a standard deviation of 10. Lower scores indicate worse quality of life.
- **SF-36 MCS**: same as above, but the Mental Composite Scale measures the impact of one's psychosocial functioning in his or her life.

Pre-Anesthesiology Measures: Summary of physical and psychosocial variables measured at the initial baseline assessment immediately after randomization.

Variable	Mean (SD)		Between Groups Significance*
	FORT	TAU	
Pain VAS	5.9 (2.1)	6.3 (1.9)	NS
MVAS	72.8 (25.7)	81.0 (22.3)	NS
BDI	11.0 (7.7)	14.0 (8.8)	NS
Lift-FW	57.3 (22.9)	51.3 (21.3)	NS
Lift-WE	42.3 (19.2)	37.9 (15.7)	NS
SF-36 PCS	34.6 (10.9)	33.6 (7.7)	NS
SF-36 MCS	53.3 (8.4)	51.1 (10.6)	NS

** NS = no significant differences between groups based on independent samples t-tests*

Pre-FORT Measures: Summary of physical and psychosocial variables measured immediately before the 3-week intervention (FORT) interval.

Variable	Mean (SD)		Between Groups Significance*
	FORT	TAU	
Pain VAS	6.0 (2.1)	5.7 (2.7)	NS
MVAS	74.8 (18.4)	78.2 (23.3)	NS
BDI	10.4 (6.1)	12.3 (11.8)	NS
Lift-FW	58.8 (24.1)	51.7 (27.1)	NS
Lift-WE	47.7 (19.0)	44.5 (18.8)	NS
SF-36 PCS	33.4 (8.5)	37.8 (7.5)	NS
SF-36 MCS	53.0 (6.9)	48.4 (13.5)	NS

* *NS = no significant differences between groups based on independent samples t-tests*

Post-FORT Measures: Summary of physical and psychosocial variables measured immediately after the 3-week intervention interval.

Variable	Mean (SD)		Between Groups Significance
	FORT	TAU	
Pain VAS	3.7 (2.2)	6.0 (2.4)	.010*
MVAS	50.7 (20.5)	83.1 (22.8)	<.001*
BDI	7.1 (4.1)	11.4 (9.5)	.110
Lift-FW	79.8 (25.3)	51.8 (16.7)	.001*
Lift-WE	64.1 (21.2)	41.5 (12.5)	.001*
SF-36 PCS	43.4 (8.4)	37.3 (8.3)	.054
SF-36 MCS	52.6 (6.8)	50.1 (8.2)	.370

* *difference is statistically significant based on independent samples t-tests*

Within-Groups Comparisons at Pre- and Post-Treatment: Summary of the extent of change in the physical and psychosocial variables within each group (FORT and TAU), between the initial and pre-intervention interval, and the pre- and post-intervention interval.

Variable	Within Groups Significance	
	Pre-Anesth → Pre-FORT	**Pre-FORT → Post-FORT**
Pain VAS		
FORT	.731	.004*
TAU	.293	.013†
MVAS		
FORT	.720	<.001*
TAU	.193	.387
BDI		
FORT	.663	.055
TAU	.575	.387
Lift-FW		
FORT	.539	<.001*
TAU	.875	.882
Lift-WE		
FORT	.016*	<.001††
TAU	.502	.502
SF-36 PCS		
FORT	.477	<.001*
TAU	.042*	.636
SF-36 MCS		
FORT	.868	.731
TAU	.386	.405

* *difference is statistically significant based on paired samples t-tests*
† *group's pain was significantly worse after the FORT interval*
†† *Post-FORT lifting capacity was significantly greater from both pre-FORT and pre-Anesthesiology at p<.001*

CONCLUSION:
Data analysis to date shows a variety of desirable outcomes. Pre-treatment between-groups analysis revealed that the groups did not initially differ significantly on any of the variables assessed, suggesting that randomization has been successful in developing two similar groups for comparison. Furthermore, examination of change in pre-treatment scores (from pre-Anesthesiology to pre-FORT) revealed few changes in the outcomes assessed within the groups, suggesting that the groups were both relatively stable during the Anesthesiology interval. This was expected because the majority of the participants seen in the study so far were already being followed for Anesthesiology pain care treatment before enrollment. The FORT group showed a significant increase in lifting capacity (from waist to eye-level) between the pre-intervention assessment intervals, and the treatment-as-usual group evidenced a significant increase in physical health-related quality of life. It is not yet clear why this occurred, but evaluation of the pre- to post-intervention within-groups changes in these scores showed that the FORT intervention resulted in significant lifting capacity increases beyond the gains made during the

pre-intervention interval, while the treatment-as-usual group showed no continued benefit for physical health-related quality of life during the intervention interval. These results indicated that, although there may have been some benefit in these domains from ongoing Anesthesiology pain care, the introduction of the interdisciplinary treatment yielded significant increases beyond those already experienced. Finally, a review of the pre- to post-treatment score changes between and within the two groups revealed significant beneficial changes in almost all domains for the FORT group compared to few beneficial changes for the TAU group. Based on these results, we can begin to conclude that the FORT intervention is of significant benefit for those who are treated, although we do not yet have enough long-term follow-up data to determine whether or not these gains can be maintained. These data support the hypothesis that an interdisciplinary functional restoration treatment program can be successfully applied in a military environment. We look forward to determining if this program can further contribute to military quality of life by helping our service members stay on active duty after developing a chronic musculoskeletal condition when they may have been otherwise medically retired.

REFERENCES

No new references included in this report.

APPENDICES

APPENDIX A: Summary of Outcome Measures in our Database

APPENDIX B: Most Recently Approved Informed Consent Document

APPENDIX A

SUMMARY OF OUTCOME MEASURES IN OUR DATABASE

ICPRP Data Management System **Variable Coding Sheet**

*** Note: Any missing data (not asked, skipped by pt, unavailable, ambiguous, more than one non-numerical answer circled, etc..) = N/A*

1	Last Name		
2	First Name		
3	FMP/SSN	3a. ___ ___ / 3b. ___ ___ ___ -- ___ ___ -- ___ ___ ___ ___	
4	Group	3b. Patient Group: ICPRP = 1 Control = 2 CODE: _____	
5	Follow-up Projected	Projected Follow-up date for PRE-I / POST-1 / 6MO / 12MO / 18MO ___ ___ / ___ ___ / ___ ___ MM DD YY	
6	Follow-up Actual	Follow-up date for PRE-I / POST-I / 6MO / 12MO / 18MO ___ ___ / ___ ___ / ___ ___ MM DD YY	
7	Date of First Appointments	4a. Date First Seen By Anesth ___ ___ / ___ ___ / ___ ___ MM DD YY	4b. Date Finished Anesth Tx ___ ___ / ___ ___ / ___ ___ MM DD YY
8	Date of Injury – LOD	5a. Date pain began ___ ___ / ___ ___ / ___ ___ MM DD YY	5b. Date Of ICPRP Intake ___ ___ / ___ ___ / ___ ___ MM DD YY
9	Age in years	_____ N/A=-9 Date of Birth: ___ ___ / ___ ___ / ___ ___ MM DD YY	6b Duration of Symptoms in months for the chief complaint N/A= -9 ___ ___ ___
10	Service of Patient (or sponsor)	US Army = 1 US Air Force =2 US Navy = 3 US Marine =4 US Coast Guard =5 N/A=-9 CODE: ____	
12	Patient's beneficiary classification:	List of Values: Active Duty.....1 Dependent of Active Duty.....2 Guard/Reserve.....3 Dependent of Guard/Reserve.....4 Retiree.....5	

		Dependent of Retiree.....6 Other.....7 Unknown.....8 N/A.....-9
13	Gender	Male.....1 Female.....2 N/A.....-9
14	Race Ethnic Code: Definition: The code which represents a non scientific division of the population based on assumed primordial biological properties combined with a segment population that possesses common characteristics and/or cultural heritage.	List of Values: American Indian or Alaskan Native.....1 Asian or Pacific Islander.....2 Black (not Hispanic).....3 White (not Hispanic).....4 Hispanic.....5 Other.....6 Unknown.....7
15	Marital Status Code: Definition: The code that	List of Values: Single, not married.....1 Married.....

	represents the marital status of the patient.	….2 Divorced……..…… …...3 Legally Separated……..……..4 Widowed……..…… …..5 Annulled…… …..6 Not defined……..7 Unknown ……8 Interlocutory decree……9 Never Married ……10
16	Years Married	_____ N/A = -9
17	Kids	Yes = 1 NO = 2 N/A = -9 If Yes, Number: _____
18	Rank of patient (or rank of spouse if pt not AD)	E-1 = 01 E-6 = 06 O-2 = 11 O-7 = 16 E-2 = 02 E-7 = 07 O-3 = 12 O-8 = 17 E-3 = 03 E-8 = 08 O-4 = 13 O-9 = 18 E-4 = 04 E-9 = 09 O-5 = 14 O-10=19 E-5 = 05 O-1 =10 O-6 = 15 N/A = -9 CODE: ____ ____
19	Years of Service	_____ N/A = -9
20	Clearance Status (check all that apply)	__ PRP __ SCI Clearance __ Flying Status __ Weapons Bearing __ Top Secret
21	Years of Education	Number of years of education: _____ N/A = -9
22	Highest Degree Received	No degree = 01 G.E.D. = 02 High School = 03 High School + Some College/Tech School = 04 Associates = 05 Bachelors = 06 Graduate = 07 N/A = -9
23	Referral Source (clinic)	Pain = 01 Neurology = 06 Hemat/Onc=11 Sleep = 02 Neuropsych = 07 Cardiology=12 Dental = 03 Ment Health = 08 Rheum =13

		Prim Care=04 Internal Med = 09 Other =14 Pulmonary=05 Orthopedics = 10 N/A = -9 CODE: ____ ____
24	Other clinic	IF Above is OTHER, specify clinic: _____
25	Current Injury	Current pain due to injury where? Lumbar = 01 Multiple Spinal = 05 Thoracic = 02 Upper Extremity = 06 Cervical = 03 Lower Extremity = 07 Other = 08
26	Patient Described	How patient describes site of injury: _____
27	Previous Injury	Previous injury/pain resulting in inability to work? YES = 01 NO = 02 N/A = -9 If YES, where? Lumbar = 01 Multiple Spinal = 05 Thoracic = 02 Upper Extremity = 06 Cervical = 03 Lower Extremity = 07 Other = 08 CODE: ___ ___
28	New Injury	Sustained new injury/pain resulting in inability to work? YES = 01 NO = 02 N/A = -9 If YES, new injury to same site? YES = 01 NO = 02 N/A = -9 If NOT SAME SITE – Site of new injury: Lumbar = 01 Multiple Spinal = 05 Thoracic = 02 Upper Extremity = 06 Cervical = 03 Lower Extremity = 07 Other = 08 CODE: ___ ___
29	Patient Described Previous Inj	How patient describes site of previous injury: _____
30	Drug Allergies	Are you allergic to any medications or food? YES = 01 NO = 02 N/A = -9 CODE: ___ ___
31	Health Care Visits	Total # of healthcare visits since pain began: _____ Total # of healthcare visits due to current injury/pain: _____
32	Type – Health Care Visits	Type of Visit(s)related to your pain: 00 None 06 Psychologist

		01 Medical Doctor 07 Licensed 02 Orthopedist Professional Counselor 03 Physical Therapist 08 Massage Therapist 04 Chiropractor 09 Acupuncturist 05 Psychiatrist 10 Other Specialist CODE-1: ___ ___ CODE-2: ___ ___ CODE-3: ___ ___
33	Hospitalizatio n	Were you hospitalized since pain began? YES = 01 NO = 02 N/A = -9 CODE: ___ ___
34	Hospitalizatio n #	If YES, how many times hospitalized? # = _____ # days in hospital = _____
35	Pain Hospitalizatio n #	How many times hospitalized due to current injury/pain? # = _____ # days in hospital = _____
36	Previous Passive Treatments?	Undergone any previous surgical/medical procedures for your pain since pain began? YES = 01 NO = 02 N/A = -9 If YES, how many procedures? _____
37	Procedure 1	If 16-6 is YES, which procedure(s)? 01 = fusion 02 = morphine pump 03 = spinal cord stimulator 04 = injection(s) 05 = TENS unit 06 = Other _____ -9 = N/A CODE: ___ ___
38	Procedure 2	If 16-6 is YES, which procedure(s)? 01 = fusion 02 = morphine pump 03 = spinal cord stimulator 04 = injection(s) 05 = TENS unit 06 = Other _____ -9 = N/A CODE: ___ ___
39	Procedure 3	If 16-6 is YES, which procedure(s)? 01 = fusion 02 = morphine pump

		03 = spinal cord stimulator 04 = injection(s) 05 = TENS unit 06 = Other _____ -9 = N/A CODE: ___ ___
40	Other Health Problems	Any other problems with your health not indicated above? YES = 01 NO = 02 N/A = -9 CODE: ___ ___
41	Sleep	17a. Average self-reported hours of sleep a night_____ N/A = -9 <u>Symptoms checked as occurring 3 or more days a week:</u> 17b.Difficulty falling asleep.....1 17c. Difficulty staying asleep.....2 17d. Waking up earlier than planned.....3 17e. Restless legs.....4 17f. Excessive snoring.....5 17g. Taking sleep medication.....6 17h. Stop breathing briefly.....7 17i. Nightmares.....8 17j Excessive daytime sleepiness.....9 17k. Not feeling rested when you wake-up.....10
42	Sleep Efficiency	17.2 <u>(Time Spent Asleep)</u> (Time Spent in Bed) * 100 = _____%
43	Sexuality	Satisfaction from 0-10 with 10 = very satisfied: N/A = -9 Code 11 if the marked "I prefer not to answer." CODE:_____
44	Alcohol Use	19a. Trouble with alcohol in the past? Yes=1 No=2 N/A = -9

		19b. Current Use: Yes =1 No =2 N/A = -9 If Yes: 19c. Average number of drinks per week: _____ 19d. Have you ever felt you should cut down on your drinking? Yes=1 No=2 19e. Have people annoyed you by criticizing your drinking? Yes=1 No=2 19f. Have you ever felt bad or guilty about your drinking? Yes=1 No=2 19g. Have you ever had a drink first thing in the morning to steady your nerves or get rid of a hangover (e.g. eye opener)? Yes=1 No=2 19h. CAGE score (0-4)_____
45	Current (past 30 days) Tobacco Use Status	20a. Not current tobacco user = 01 Prior tobacco user = 02 Current tobacco user (any daily use) = 03 N/A = -9 20b. If yes to current tobacco use: Type of tobacco Cigarettes = 01 Pipe/Cigar = 02 Smokeless = 03 20c. Duration of Tobacco Use in Years:_____
46	Current Caffeine Use	21a. Yes =01 No =02 N/A = -9 21b. If Yes: Average number of drinks per week: _____
47	BMI	22-1a. Height (inches) _____ 22-1b. Weight (pounds) _____
48	Diet	22-2. Currently on a diet trying to lose wt? Yes = 01 No = 02 N/A = -9
49	Diet – 2	Do you eat too much/too little? YES = 1 NO = 2 N/A = -9
50	Exercise on Regular Basis	Yes = 1 No = 2 N/A = -9
51	History of	

	Mental Health Treatment (any tx the pt indicated as MH including Chaplain, etc…)	Yes = 1 No = 2 N/A = -9
52	History of Physical, Sexual, or Emotional abuse	Yes = 1 No = 2 N/A = -9
53	Satisfaction with Social Support from Family & Friends	Very Unsatisfied……1 Unsatisfied……2 Satisfied……3 Very Satisfied……4 N/A……-9
54	Hours Worked	How many hours a week, on average, do you work? _____
55	Job History	26a. Disability/Workers Comp: Yes = 1 No = 2 N/A = -9 <u>26b. Work Status:</u> Full-time outside the home……1 Full-time in the home……2 Part-time……3 Retired……4 N/A……-9 <u>26c. Job Title:</u> What is your current job title? _____

		26c. If Working, Satisfaction with Current Occupation: Very Unsatisfied.....1 Unsatisfied..... .....2 Satisfied..... .....3 Very Satisfied..... 4 N/A..... .....-9
56	Return to Work	Present Vocational Status: 01 RTW, Full Time, Same Job Type 02 RTW, Full Time, New Job Type 03 RTW, Light/Part Duty, Same Job Type 04 RTW, Light/Part Duty, New Job Type **05 RTW, But Not Pres Worki BC of New Injury** 06 RTW, But Not Pres Work BC Original Injury 07 Self-Employed 08 Vocational Training or School/Retraining 09 Never Returned to Work Because of Injury 10 Denies Work BC of Employment Factors Exc 11 Denies Work, But Engag in Incom Prod Act 12 Denies Work,Participates Non-Income Prod Activities 13 Was Not Working Before Injury
57	RTW Date	Date pt returned to work: ___ ___ / ___ ___ / ___ ___ MM DD YY
58	Quality of Life	Satisfaction with Quality of Life: Very Unsatisfied.....1 Unsatisfied..... .....2 Satisfied..... .....3 Very Satisfied..... 4 N/A..... .....-9
59	Spirituality	28a. Importance from 0-10 with 10 = very important: ____

		N/A=-9 28b. Current difficulties affecting spirituality: Yes = 1 No= 2
60	Legal Issues	Current litigation pending concerning pt's condition: Yes = 1 No= 2 N/A=-9
61	Disciplinary Action	Any history of disciplinary action (e.g., LOC, LOR, LOA)? YES = 01 NO = 02 N/A = -9
62	Goals	Top Three Goals from Goal sheet (1-51) 1:____ 2:____ 3:____ N/A=-9
63	PrimaryAxis I Diagnosis	296.2 MD, sing ep = 01 316 Psych fac/Med Cond= 06 296.3 MD, recurrent = 02 V71.09 No diagnosis = 07 307.xx Pain Disorder = 03 799.9 Deferred = 08 307.42 Prim Insomnia = 04 Other Diagnosis = 09 309.xx Adjustment DO= 05 PTSD = 10 GAD = 11 Panic Dis = 12 N/A=-9 CODE: ____ ____
64	Other diagnosis	IF above is OTHER, specify diagnosis:
65	Secondary Axis I Diagnosis if appropritate	296.2 MD, sing ep = 01 316 Psych fac/Med Cond= 06 296.3 MD, recurrent = 02 V71.09 No diagnosis = 07 307.xx Pain Disorder = 03 799.9 Deferred = 08 307.42 Prim Insomnia = 04 Other Diagnosis = 09 309.xx Adjustment DO= 05 N/A=-9 CODE: ____ ____
66	Other diagnosis	IF above is OTHER, specify diagnosis:
67	Primary Axis III (Choose ONE most directly related to referral)	Headache=01 Fibromyalgia = 08 Myofac. Pain = 15 RSD/CRPS=02 HTN= 09 Other = 16 IBS = 03 Other chron pain=10 N/A=-9 TMD = 04 Cardiac = 11 COPD = 05 Cancer =12 Arthritis = 06 Obesity = 13 Chron Back= 07 Insomnia = 14 CODE: ____ ____
68	Other Axis III	IF above is OTHER, specify diagnosis:

69	Secondary Axis III	Headache=01 Fibromyalgia = 08 Myofac. Pain = 15 RSD/CRPS=02 HTN= 09 Other = 16 IBS = 03 Other chron pain=10 N/A=-9 TMD = 04 Cardiac = 11 COPD = 05 Cancer =12 Arthritis = 06 Obesity = 13 Chron Back= 07 Insomnia = 14 CODE: ____ ____
70	Other Axis III	IF above is OTHER, specify diagnosis:
71	Site Treated	WHMC = 01 BAMC = 02 CODE: ____ ____

JOB REQUIREMENTS EVALUATION

72	Standing	Indicate the amount of time spent at your job doing this activity: NONE = 01 OCCASIONAL = 02 FREQUENT = 03 CONSTANT = 04 CODE: ___ ___
73	Walking	Indicate the amount of time spent at your job doing this activity: NONE = 01 OCCASIONAL = 02 FREQUENT = 03 CONSTANT = 04 CODE: ___ ___
74	Sitting	Indicate the amount of time spent at your job doing this activity: NONE = 01 OCCASIONAL = 02 FREQUENT = 03 CONSTANT = 04 CODE: ___ ___
75	Squatting	Indicate the amount of time spent at your job doing this activity: NONE = 01 OCCASIONAL = 02 FREQUENT = 03 CONSTANT = 04 CODE: ___ ___
76	Kneeling	Indicate the amount of time spent at your job doing this activity: NONE = 01 OCCASIONAL = 02 FREQUENT = 03 CONSTANT = 04 CODE: ___ ___
77	Stooping/Bending	Indicate the amount of time spent at your job doing this activity: NONE = 01 OCCASIONAL = 02 FREQUENT = 03 CONSTANT = 04 CODE: ___ ___
78	Crawling	Indicate the amount of time spent at your job doing this activity: NONE = 01 OCCASIONAL = 02 FREQUENT = 03 CONSTANT = 04 CODE: ___ ___
79	Driving	Indicate the amount of time spent at your job doing this activity: NONE = 01 OCCASIONAL = 02 FREQUENT = 03 CONSTANT = 04 CODE: ___ ___
80	Repetitive Handwork	Indicate the amount of time spent at your job doing this activity: NONE = 01 OCCASIONAL = 02 FREQUENT = 03 CONSTANT = 04 CODE: ___ ___
81	Reaching	Indicate the amount of time spent at your job doing this activity: NONE = 01 OCCASIONAL = 02 FREQUENT = 03 CONSTANT = 04 CODE: ___ ___
82	Lifting	Indicate the amount of time spent at your job doing this activity: NONE = 01 OCCASIONAL = 02 FREQUENT = 03 CONSTANT = 04 CODE: ___ ___
83	Carrying	Indicate the amount of time spent at your job doing this activity: NONE = 01 OCCASIONAL = 02 FREQUENT = 03 CONSTANT = 04 CODE: ___ ___
84	Pushing/Pulling	Indicate the amount of time spent at your job doing this activity: NONE = 01 OCCASIONAL = 02 FREQUENT = 03 CONSTANT = 04 CODE: ___ ___
85	Climbing	Indicate the amount of time spent at your job doing this activity: NONE = 01 OCCASIONAL = 02 FREQUENT = 03 CONSTANT = 04 CODE: ___ ___

PSYCHOSOCIAL TEST DATA

Reminder: Any missing data (unavailable, ambiguous, more than answer circled, etc..) = N/A

86	BDI – Front	____ ____		102	MPIPS	____ ____ . ____
87	BDI - Back	____ ____		103	MPII	____ ____ . ____
88	BDI - Total	____ ____		104	MPILC	____ ____ . ____
89	BDI – Item 9	____ ____		105	MPIAD	____ ____ . ____
90	SF36 – PF	____ ____		106	MPIS	____ ____ . ____
91	SF36 – RP	____ ____		107	MPIPR	____ ____ . ____
92	SF36 – BP	____ ____		108	MPISR	____ ____ . ____
93	SF36 – GH	____ ____		109	MPIDR	____ ____ . ____
94	SF36 – VT	____ ____		110	MPIHC	____ ____ . ____
95	SF36 – SF	____ ____		111	MPIOW	____ ____ . ____
96	SF36 – RE	____ ____		112	MPIAAH	____ ____ . ____
97	SF36 – MH	____ ____		113	MPISA	____ ____ . ____
98	SF36 – PCS	____ ____		114	MPIGA	____ ____ . ____
99	SF36 – MCS	____ ____		115	MPI Profile	Dysfunctional……..

100	SF36 – PCS %	____ ____				1 Interpers/Distr……. 2 Adaptive Cop……..3 Anomolous……. 4 Hybrid……. 5 Unanalyzable…….. 6
101	SF36 – MCS %	____ ____		116	PCI	High: _____ Low: _____ AVG: _____

Reminder: Any missing data (unavailable, ambiguous, more than answer circled, etc..) = N/A

117	SF36q1	____ ____	133	SF36q17	____ ____ . ____ ___
118	SF36q2	____ ____	134	SF36q18	____ ____ . ____ ___
119	SF36q3	____ ____	135	SF36q19	____ ____ . ____ ___
120	SF36q4	____ ____	136	SF36q20	____ ____ . ____ ___
121	SF36q5	____ ____	137	SF36q21	____ ____ . ____ ___
122	SF36q6	____ ____	138	SF36q22	____ ____ . ____ ___
123	SF36q7	____ ____	139	SF36q23	____ ____ . ____ ___
124	SF36q8	____ ____	140	SF36q24	____ ____ . ____ ___
125	SF36q9	____ ____	141	SF36q25	____ ____ . ____ ___
126	SF36q10	____ ____	142	SF36q26	____ ____ . ____

127	SF36q11	_____ _____		143	SF36q27	____ ____ . ____ ___
128	SF36q12	_____ _____		144	SF36q28	____ ____ . ____ ___
129	SF36q13	_____ _____		145	SF36q29	____ ____ . ____ ___
130	SF36q14	_____ _____		146	SF36q30	____ ____ . ____ ___
131	SF36q15	_____ _____		147	SF36q31	____ ____ . ____ ___
132	SF36q16	_____ _____		148	SF36q32	____ ____ . ____ ___

149	SF36q33	_____ _____	164	THQgc	____ ____ . ____ ____
150	SF36q34	_____ _____	165	FABQpa	____ ____ . ____ ____
151	SF36q35	_____ _____	166	FABQw	____ ____ . ____ ____
152	SF36q36	_____ _____	167		____ ____ . ____ ____
153	MVAS	_____ _____	168	PainVAS	____ ____ . ____ ____
154	MVAScat	0 = None (MVAS = 0) 1 = Mild (1-40) 2 = Moderate (41-70) 3 = Severe (71-100) 4 = Very Severe (101-130) 5 = Extreme (131-150) -9 = no MVAS score	169	POMStot	____ ____ . ____ ____
			170	POMSanx	____ ____ . ____ ____
155	THQwp	_____ _____	171	POMSdep	____ ____ . ____ ____
156	THQmed	_____ _____	172	POMSang	____ ____ . ____ ____
157	THQpsy	_____ _____	173	POMSvig	____ ____ . ____ ____
158	THQpt	_____ _____	174	POMSfat	____ ____ . ____ ____
159	THQdr	_____ _____	175	POMScon	____ ____ . ____ ____
160	THQip	_____ _____	176		____ ____ . ____

161	THQdiag	____ ____		177		____ ____ . ____ ____
162	THQwat	____ ____		178	ORQtot	____ ____ . ____ ____
163	THQpe	____ ____		179	ORQdep	____ ____ . ____ ____

180	ORQpi	_____ _____	
181	ORQdwr	_____ _____	
182	ORQpwh	_____ _____	
183	ORQssw	_____ _____	
184	ORQwsl	_____ _____	
185	ORQwks	_____ _____	
186	ORQfss	_____ _____	
187	ORQppwr	_____ _____	
188	PCLM	_____ _____	
189	OSW	_____ _____	
190	ISI	_____ _____	
191	CEQ	_____ _____	

DSM-IV AXIS I DIAGNOSIS

192	AxisId1	1 = Major Dep – Single Episode (296.2) 2 = Major Dep – Recurrent (296.3) 3 = Pain Disorder (307.xx) 4 = Primary Insomnia (307.42) 5 = Adjustment Disorder (309.xx) 6 = Psych Fac to Med Cond (316) 7 = Gen Anx Dis (300.02) 8 = PTSD (309.81) 9 = Panic Disorder (300.2x) 10 = Deferred (799.9) 11 = No Diagnosis (V71.09) 12 = Other Diagnosis -9 = N/A
193	AxisId2	1 = Major Dep – Single Episode (296.2) 2 = Major Dep – Recurrent (296.3) 3 = Pain Disorder (307.xx) 4 = Primary Insomnia (307.42) 5 = Adjustment Disorder (309.xx) 6 = Psych Fac to Med Cond (316) 7 = Gen Anx Dis (300.02) 8 = PTSD (309.81) 9 = Panic Disorder (300.2x) 10 = Deferred (799.9) 11 = No Diagnosis (V71.09) 12 = Other Diagnosis -9 = N/A
194	AxisId3	1 = Major Dep – Single Episode (296.2) 2 = Major Dep – Recurrent (296.3) 3 = Pain Disorder (307.xx) 4 = Primary Insomnia (307.42) 5 = Adjustment Disorder (309.xx) 6 = Psych Fac to Med Cond (316) 7 = Gen Anx Dis (300.02) 8 = PTSD (309.81) 9 = Panic Disorder (300.2x) 10 = Deferred (799.9) 11 = No Diagnosis (V71.09) 12 = Other Diagnosis -9 = N/A

FCE DATA

195	Tflex	_____ _____	
196	Text	_____ _____	
197	PILEwt-waist	_____ _____	
198	PILEhr-waist	_____ _____	
199	PILEwt-shoulder	_____ _____	
200	PILEhr-shoulder	_____ _____	
201	Aerovo2	_____ _____	
202	Aerotime	_____ _____	
203	Aerohr	_____ _____	
204	Aeroefft	_____ _____	
205	GripstrL	_____ _____	
206	GripstrR	_____ _____	
207	DomHand	*Circle one:* **Left** **Right**	

Past Treatment Received

Reminder: Any missing data (unavailable, ambiguous, etc..) = N/A

208	Individual	No.....0 Yes.....1 Intake Only.....2 Number of Sessions:_____
209	Biofeedback	No.....0 Yes.....1 Number of Sessions:_____
210	Interdisciplinary Chronic Pain Management Program *or* Interdisciplinary Chronic Pain Rehabilitation Program Pain Group	No.....0 Yes.....1 Number of Sessions:_____
211	4-session Pain Group or similar	No.....0 Yes.....1 Number of Sessions:_____
212	TMD Group	No.....0 Yes.....1 Number of Sessions:_____
213	COPD (Pulmonary Rehab Group)	No.....0 Yes.....1 Number of Sessions:_____
21	LEARN	

4		No..... ...0 Yes..... 1 Number of Sessions:_____
215	Behavioral Cardiac Rehab Program	No..... ...0 Yes..... 1 Number of Sessions:_____
216	Tobacco Cessation Program	No..... ...0 Yes..... 1 Number of Sessions:_____
217	Relaxation Group	No..... ...0 Yes..... 1 Number of Sessions:_____
218	Insomnia Group	No..... ...0 Yes..... 1 Number of Sessions:_____
219	Previous Passive Treatments?	Undergone any previous surgical/medical procedures for your pain since pain began? YES = 01 NO = 02 N/A = -9 If YES, how many procedures? _____
220	Procedure 1	If 16-6 is YES, which procedure(s)? 01 = fusion 02 = morphine pump 03 = spinal cord stimulator 04 = injection(s)

		05 = TENS unit 06 = Other _____ -9 = N/A CODE: ___ ___
221	Procedure 2	If 16-6 is YES, which procedure(s)? 01 = fusion 02 = morphine pump 03 = spinal cord stimulator 04 = injection(s) 05 = TENS unit 06 = Other _____ -9 = N/A CODE: ___ ___
222	Procedure 3	If 16-6 is YES, which procedure(s)? 01 = fusion 02 = morphine pump 03 = spinal cord stimulator 04 = injection(s) 05 = TENS unit 06 = Other _____ -9 = N/A CODE: ___ ___

Post-FORT Treatment(s) Received

Reminder: Any missing data (unavailable, ambiguous, etc..) = N/A

223	Individual	No..... ...0 Yes..... 1 Intake Only .....2 Number of Sessions:_____
224	Biofeedback	No..... ...0 Yes..... 1 Number of Sessions:_____
225	Interdisciplinary Chronic Pain Management Program *or* Interdisciplinary Chronic Pain Rehabilitation Program Pain Group	No..... ...0 Yes..... 1 Number of Sessions:_____
226	4-session Pain Group or similar	No..... ...0 Yes..... 1 Number of Sessions:_____
227	TMD Group	No..... ...0 Yes..... 1 Number of Sessions:_____
228	COPD (Pulmonary Rehab Group)	No..... ...0 Yes..... 1 Number of Sessions:_____
22	LEARN	

9		No…… …0 Yes…….. 1 Number of Sessions:_____
230	Behavioral Cardiac Rehab Program	No…… …0 Yes…….. 1 Number of Sessions:_____
231	Tobacco Cessation Program	No…… …0 Yes…….. 1 Number of Sessions:_____
232	Relaxation Group	No…… …0 Yes…….. 1 Number of Sessions:_____
233	Insomnia Group	No…… …0 Yes…….. 1 Number of Sessions:_____
234	Passive Treatments?	Undergone any previous surgical/medical procedures for your pain since completing the FORT program? YES = 01 NO = 02 N/A = -9 If YES, how many procedures? _____
235	Procedure 1	If 16-6 is YES, which procedure(s)? 01 = fusion 02 = morphine pump 03 = spinal cord stimulator 04 = injection(s)

		05 = TENS unit 06 = Other _____ -9 = N/A CODE: ___ ___
23 6	Procedure 2	If 16-6 is YES, which procedure(s)? 01 = fusion 02 = morphine pump 03 = spinal cord stimulator 04 = injection(s) 05 = TENS unit 06 = Other _____ -9 = N/A CODE: ___ ___
23 7	Procedure 3	If 16-6 is YES, which procedure(s)? 01 = fusion 02 = morphine pump 03 = spinal cord stimulator 04 = injection(s) 05 = TENS unit 06 = Other _____ -9 = N/A CODE: ___ ___

APPENDIX B

MOST RECENTLY APPROVED ICD

FWH20030036H
BROOKE ARMY MEDICAL CENTER/WILFORD HALL MEDICAL CENTER
INFORMED CONSENT DOCUMENT
(ICD Template Version 4. Feb 02)

A Randomized Trial of Musculoskeletal Pain Treatment in a Military Population

PRINCIPAL INVESTIGATOR – Lt Col Alan L. Peterson

If you choose not to participate in this research study, your decision will not affect your eligibility for care or any other benefits to which you are entitled.

DESCRIPTION/PURPOSE OF RESEARCH
You are being asked to consider participation in this research study. The purpose of this study is to evaluate the effectiveness of two different treatments designed to decrease chronic pain, increase functioning, and retain military members on active duty.

This study is being conducted at Wilford Hall Medical Center in San Antonio, Texas and Brooke Army Medical Center, San Antonio, Texas. The study will enroll approximately 90 active duty military personnel with musculoskeletal pain over a period of 18 months. The overall duration of the study will be about 4 years, but the time requirement for individual participants will be about four weeks with follow-up evaluations occurring at 6 months, 12 months, and 18 months.

The two approaches to pain management that will be evaluated in this study are as follows:

Group A, Standard Anesthesia Pain Clinic Medical Care: Participants in this group will be thoroughly evaluated by physicians trained in medical pain management techniques. Appropriate medical recommendations will be made and may include any of the following: pain medications, antidepressant medications, and nerve block and steroid injections. This treatment will include about 6 patient visits over a three-week period.

Group B, Standard Anesthesia Pain Clinic Medical Care AND Interdisciplinary Chronic Pain Rehabilitation Program: This group will receive all of the treatment as described in Group A above, as well as an interdisciplinary functional restoration treatment program, which consists of three major components. Each participant will be evaluated and treated by physical therapy, occupational therapy, and clinical health psychology in coordination with a supervising nurse-physician team. This group will include 3 weeks of full-time treatment including supervised physical exercise and learning pain management skills.

RANDOMIZATION OF STUDY PARTICIPANTS: As a participant, you will be randomly assigned to one of these two groups. Randomization is a process much like flipping a coin and means you will have the same chance of being assigned to either of these two groups.

PROCEDURES: As a participant, you will undergo the following procedures:

Meeting One: The first meeting with Clinical Health Psychology service will involve a full assessment of your pain condition. You will then receive an overview of the study, complete the informed consent document, and be asked to complete several questionnaires about your functioning in many areas (estimated time 1 1/2 hours).

During the first session you will also be randomly assigned to one of the two groups. If you are assigned to Group A or B, you will be treated at the Anesthesia Pain Clinic at Wilford Hall or Brooke Army Medical Center as directed by your physicians. Should it be necessary for you to have a standard anesthesia pain clinic treatment requiring additional informed consent, a separate consent form will be completed at the time of the procedure. If you are selected for Group B, you will also be scheduled for inclusion in the Interdisciplinary Chronic Pain Rehabilitation Program. This three-week program will be offered at Wilford Hall Medical Center once each month.

Phone Contacts and Mailings: Participants in both Groups A and B will be contacted for follow-up information 3 weeks after the initiation of treatment and then at the 6 month, 12 month and 18 month point. Each of these follow-up contacts will involve gathering the same information on functioning as previously assessed. I understand that if I am no longer on active duty in the U.S. military at the time of one of my follow-up assessments, I will be contacted at my civilian address to request completion of the outcome questionnaires.

Should it be necessary for you to have a procedure requiring additional informed consent, a separate consent form will be completed at the time of the procedure.

RISKS OR DISCOMFORTS:

There is minimal psychological and/or physical risk from the early interventions to be used in this study. In past research, none of the subjects had any problems. You could experience stress from participating in this kind of research. Knowing that researchers have personal information about you may trouble you. There is a possibility that your low back pain may worsen if you are assigned to the early intervention; however, this is not anticipated.

For those in Group A and B, the risks and discomforts of participating are the same as those that would be expected when under the care of the Anesthesia Pain Clinic for any other patient. An additional informed consent for a standard anesthesia pain clinic treatment may be obtained at the time of treatment. These treatments include the use of medications and injections, and the potential adverse effects include infection, bleeding, nerve damage, allergic reactions and either no change or a worsening of your pain.

For those in Group B, there are some risks, which involve engaging in a functional restoration program although these are expected to be minimized since you will be following the recommendations of an interdisciplinary staff of healthcare providers (e.g., physician, nurse, psychologist, physical therapist, and occupational therapist). It is also possible that your pain could become somewhat worse during the course of treatment. There may also be unforeseen risks associated with this study. A previously unknown problem could result from your participation in this research. It is not possible to estimate the chances of such problems or how serious problems could be. Consequently, we ask that you inform the study doctor or any of the

Investigators listed on this form of any problems that arise during this study, and also inform your physician. Finally, if you should ever report current or recent thoughts, plan or intent to harm or kill yourself or evidence of self-harm is ever indicated during the course of your participation in this study, your commander will be notified and appropriate action will be taken to help ensure your safety, including assessment of risk by a credentialed Mental Health Provider and referral to an appropriate level of care (e.g., outpatient follow-up or inpatient hospitalization).

BENEFITS:

While there is no guarantee you will benefit from participating in this study, it is intended to reduce your pain, increase your functioning, and retain your active duty status. The treatments are believed to be beneficial, and how well they work is the focus on this study. The investigators have designed this study to learn if there is a difference and how they can better treat active duty members who often times are concerned about their ability to remain in the military until they decide to retire. There will also be a scientific benefit if this study can tell us which treatment for musculoskeletal pain is better.

PAYMENT (COMPENSATION):
You will not receive any compensation (payment) for participating in this study.

ALTERNATIVES TO PARTICIPATION: Alternatives may be available to you, including other pain management programs or individual consultations with Physical Therapy, Occupational Therapy, Mental Health, or Clinical Health Psychology available through your medical treatment facility. Other alternatives would be to seek follow-up care with your primary care manager or to participate in treatment at the Anesthesia Pain Clinic but to decline participation in the data collection or to decline any treatment at all.

CONFIDENTIALITY OF RECORDS OF STUDY PARTICIPATION:
Records of your participation in this study may only be disclosed in accordance with federal law, including the Federal Privacy Act, 5 U.S.C. 552a, and its implementing regulations. DD Form 2005, Privacy Act Statement- Military Health Records, contains the Privacy Act Statement for the records. By signing this consent document, you give your permission for information gained from your participation in this study to be published in medical literature, discussed for educational purposes, and used generally to further medical science. You will not be personally identified; all information will be presented as anonymous data.

Your records may be reviewed by the U.S. Food & Drug Administration (FDA), other government agencies, the BAMC/WHMC Institutional Review Boards, and by research staff. Further, representatives of the U.S. Army Medical Research and Materiel Command are eligible to review research records as a part of their responsibility to protect human subjects in research. Complete confidentiality cannot be promised, particularly for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities.

ENTITLEMENT TO CARE:

In the event of injury resulting from this study, the extent of medical care provided is limited and will be within the scope authorized for Department of Defense (DoD) health care beneficiaries.

Your entitlement to medical and dental care and/or compensation in the event of injury is governed by federal laws and regulations, and if you have questions about your rights as a research subject or if you believe you have received a research-related injury, you may contact the Wilford Hall Clinical Research Squadron Commander, (210) 292-7069 or Wilford Hall Medical Center Risk Manager, 210-292-6004.
Brooke Army Medical Center Protocol Coordinators, 210-916-2598 or BAMC Judge Advocate, 210-916-2031.

Preparation in this study does not alter your ongoing medical benefits as a military beneficiary, and you will continue to receive any needed medical treatment should you experience illness or injury as a result of this study. In the event of injury resulting from the investigational procedures, the extent of medical care provided is limited and will be within the scope authorized for DoD health care beneficiaries.

BLOOD & TISSUE SAMPLES: "No blood or tissue samples will be taken as part of this study."

STATEMENT OF GOOD FAITH: The investigator cannot guarantee or promise that you will receive benefits from this study; however, the investigator will keep you informed of any serious complications, which may result from your participation in this study.

VOLUNTARY PARTICIPATION:
The decision to participate in this study is completely voluntary on your part. No one has coerced or intimidated you into participating in this project. You are participating because you want to. Lt Col (Dr) Alan Peterson, (Wilford Hall Medical Center, DSN 554-5968, Commercial (210) 292-5968), Dr. Robert Gatchel, (University of Texas Southwest Medical Center, Dallas and the University of Texas at Arlington, (817) 272-1207), or one of their associates has adequately answered any and all questions you have about this study, your participation, and the procedures involved. Dr. Peterson, Dr. Gatchel, or a member of the Clinical Health Psychology staff at Wilford Hall Medical Center ((210) 292-5968) will be available to answer any questions concerning procedures throughout this study. If significant new findings develop during the course of this study that may relate to your decision to continue participation, you will be informed.

You may withdraw this consent at any time and discontinue further participation in this study without affecting your eligibility for care or any other benefits to which you are entitled. Should you choose to
withdraw, you must inform one of the investigators. Your condition will continue to be treated in accordance with acceptable standards of medical treatment.

The investigator of this study may terminate your participation in this study at any time if he/she feels this to be in your best interest. Your consent to participate in this study is given on a voluntary basis. All oral and written information and discussions about this study have been in English, a language in which you are fluent.

CONTACT INFORMATION:

Principal Investigator (PI)
The principal investigator or a member of Clinical Health Psychology staff will be available to answer any questions concerning procedures throughout this study.

Principal Investigator: Lt Col Alan L. Peterson Phone: (210) 292-5968

Institutional Review Board (IRB)
The WHMC Institutional Review Board (IRB), the hospital committee responsible for safeguarding your rights as a research subject, has assigned a member of the IRB, who is not part of the study team, to serve as an outside monitor for this study (this person is the Medical Monitor). If you have any questions about your rights as a research subject or any other concerns that cannot be addressed by the PI, you can contact the medical monitor, Joseph Schmelz, PhD, RN at (210) 292-5687. Or mail to: 59th Clinical Research Squadron/MSRP, 1255 Wilford Hall Loop, Lackland Air Force Base, Texas 78236.

In addition, if you have any comments, questions, concerns or complaints, you may also contact the Chairperson of the IRB, at (210) 292-7558. Or mail to: 59th Medical Wing/CM, 2200 Bergquist Drive, Lackland Air Force Base, Texas 78236.

A copy of this form has been given to you.

_____ _____-____-_____ _____
VOLUNTEER'S SIGNATURE **VOLUNTEER'S SSN** **DATE**

_____ _____ _____-____-_____
VOLUNTEER'S PRINTED NAME **FMP** **SPONSOR'S SSN** **DOB**

_____
VOLUNTEER'S ADDRESS (street, city, state, zip)

_____ _____ ____-____-_____
ADVISING INVESTIGATOR'S SIGNATURE **DATE** **(PHONE NUMBER)**
(can only be signed by an investigator whose name is listed in the protocol)

_____
PRINTED NAME OF ADVISING INVESTIGATOR

_____ _____
WITNESS' SIGNATURE **DATE**

(Must witness ALL signatures)

_____

PRINTED NAME OF WITNESS

_____

Subject's Stamp Plate
PRIVACY ACT OF 1974 APPLIES.
DD FORM 2005 FILED IN MILITARY HEALTH RECORDS

February 11, 2004

U.S. Army Medical Research and Materiel Command (MCMR-RMI-S)
504 Scott Street
Fort Detrick, MD 21702-5012

RE: DAMD17-03-1-0055

Dear Research Command:

In accordance with your letter of December 18, 2003, we are enclosing the original and two copies of the first Annual Report for the referenced award.

As requested, the PI's current contact information is on the letterhead.

If we may be of further assistance to you, please advise.

Sincerely yours,

Robert J. Gatchel, Ph.D.
Principal Investigator

Perrie M. Adams, Ph.D.
Associate Dean for Research

RJG:cag